



**CURRENT AWARENESS OF GENETICALLY  
MODIFIED FOOD ISSUES**

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## **SUMMARY**

This report is one of a series intended to provide the New Zealand Food Safety Authority with an independent source of current information on issues related to genetically modified foods. This report covers developments in the period July 2002 to January 2003.

## 1 INTRODUCTION

This project is intended to provide the New Zealand Food Safety Authority with an independent source of current information on genetically modified foods (GMFs). It is intended to include:

- scientific issues concerning safety, detection, and nutritional quality of genetically modified foods;
- the legislative situation overseas.

The aim is to condense this material into a useful form so that the Authority can respond to issues and enquiries from other government agencies, industry and the general public. The project also aims to provide information to support the development of an appropriate enforcement strategy on standards for genetically modified foods.

This is the first report for the 2002/2003 year and covers events from June 2002 to January 2003.

Wider issues concerned with environmental or social effects of genetic modification and genetically modified organisms (GMOs), biodiversity, gene transfer, insect resistance, etc., are only covered peripherally in this report. This reflects the division of responsibility for genetically modified material, between the New Zealand Food Safety Authority and Food Standards Australia New Zealand (FSANZ) for GMFs on one hand, and the Environmental Risk Management Authority (ERMA) for GMOs on the other.

For consistency, some alternative terms have been standardised in this report. “Corn” and “maize” are interchangeable; in this document “corn” is used throughout. Canola is a genetic variation of rapeseed (or oilseed rape) developed by traditional plant breeding to be low in both erucic acid and glucosinolates (“double low” variety). In this document “rapeseed/canola” is used throughout.

Abbreviations used throughout this document:

EU: European Union

FDA: Food and Drug Administration (US)

USDA: United States Department of Agriculture

EPA: Environmental Protection Agency (US)

MAFF: United Kingdom Ministry of Agriculture Fisheries and Food

ACNFP: Advisory Committee on Novel Foods and Processes (UK)

ACRE: Advisory Committee on Releases to the Environment (UK)

ERMA: Environmental Risk Management Authority

ANZFA: Australia New Zealand Food Authority

An important source for this project is the AgNet email newsletter produced by staff at the University of Guelph. Information and archives of the newsletter can be found at:

<http://www.plant.uoguelph.ca/safefood/>

## 2 DETECTION OF GENETICALLY MODIFIED FOODS: RECENT DEVELOPMENTS

### 2.1 Codex Committee on Methods of Analysis and Sampling

The Twenty-fourth Session of the Codex Committee on Methods of Analysis and Sampling (CCMAS) was held Budapest in November 2002. This meeting included in its agenda consideration of the methods for the detection and identification of foods derived from biotechnology that were referred to it by the third meeting of the Codex *ad hoc* Task Force on Foods Derived From Biotechnology in March 2002. In addition to the list of methods considered by the Task Force to be validated, a discussion paper was prepared for CCMAS on a General Approach and Criteria for the Methods. This paper concluded that “in view of the difficulty of practical application in this area, it is recommended that CCMAS discuss at its Twenty Fourth Session the formation of an *ad hoc* Working Group to develop recommendations both with respect to quality control measures that a laboratory offering GMO analyses should undertake, and specific criteria for methods of analysis to supplement the general criteria recommended in CX/MAS 02/05.”

The full list of methods and discussion paper are available from:

[http://www.codexalimentarius.net/ccmas24/ma02\\_01e.htm](http://www.codexalimentarius.net/ccmas24/ma02_01e.htm)

The results of the meeting have been reported (Alinorm 03/23 see: [ftp://ftp.fao.org/codex/alinorm03/AI03\\_23e.pdf](ftp://ftp.fao.org/codex/alinorm03/AI03_23e.pdf)). Essentially the meeting decided that in the absence of a specification for which these methods were required, the methods could not be endorsed by CCMAS. Continued work on criteria for selection of methods was supported, to be conducted by a Working Group led by Germany and the UK.

The following relevant section is taken from the report of the US delegation to the CCMAS meeting (see: [http://www.fsis.usda.gov/OA/codex/rep\\_mas02.htm](http://www.fsis.usda.gov/OA/codex/rep_mas02.htm)).

“The Committee agreed that a Working Group led by Germany and the United Kingdom and including the U.S. would update and further develop the paper prepared for this Session on the general approach and criteria for methods used for the detection and identification of foods derived from biotechnology. In view of the absence of specific Codex provisions and the difficulties with the practical application of methodology in this area, it was decided that the revised paper would include additional recommendations for quality control measures in laboratories and criteria for selection of methods of analysis that will be considered by the next Session of the Committee.

The Committee considered the List of methods developed and forwarded by the *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology. It noted that the List provided a good review of methods currently used by Member Governments in the area of GM material analysis and was available in document CX/MAS 02/8 for reference. The Committee agreed with the view of the Delegation of the United States that selection or endorsement of methods without appropriate provisions was not possible. It agreed to focus on the criteria and quality control measures to be elaborated by the Working Group for consideration by the Committee at the next Session.”

## **2.2 Detection of Bt protein in corn made into ethanol**

Scientists at the USDA have been studying the fate of the Bt protein in GM corn during the process of converting corn into ethanol (this has implications for potential detection of GM material). Both wet and dry milling processes were studied, using an immunoassay for the Cry1Ab protein. During dry milling the use of heat to liquefy corn meal quickly destroyed the protein and there was no trace of it in the mash or resulting ethanol. In wet milled corn Bt protein could be detected in whole kernels, gluten, germ oil and fibre, but not in the starch or steep liquor fraction used to produce the ethanol. See:

<http://www.ars.usda.gov/is/AR/archive/jul02/track0702.htm>

## **2.3 Agriquality purchases Genescan laboratory**

The New Zealand State Owned Enterprise Agriquality has purchased the Melbourne laboratory of Genescan, which conducts testing of food, feed and seeds for GM material See: <http://www.agriquality.com.au>

## **2.4 European network of GMO laboratories**

The European Commission officially launched a network of GM analytical laboratories in December 2002. The 45 control laboratories in EU member states will develop and validate methods for detecting and quantifying GMOs in food and feed. Activities will be co-ordinated by the European Commission's Joint Research Centre (see: <http://biotech.jrc.it/>). This formalises a network that has been co-ordinating their efforts for approximately 2 years.

### **3 GMF APPROVALS**

Previous issues of this report have periodically included a table that listed approvals for human food use of GM transformation events. It has been decided to discontinue this table, in preference to the more extensive data at the AgBios database. This database covers human food use approvals as well as animal feed and environmental approvals, and some details about the genetic material inserted into each crop. The database is accessible at:

<http://www.agbios.com/default.asp>

Developments during the report period are summarised below.

#### **3.1 Japan**

In June 2002 it was announced that Japan had approved a variety of GM corn, Herculex I Transformation Event TC1507 developed by Dow Agrosiences (Mycogen) and Pioneer HiBred, for food, feed and import (Source: Press release, National Corn Growers Association 24 June 2002 via AgNet). This variety of corn, like many others, contains a Bt toxin which makes it resistant to the European corn borer. However, the difference is that the variety of Bt toxin expressed by this plant is the Cry1F type. Herculex I has already been approved for food and feed use in the US and was later approved in Canada in October 2002.

Japan has also approved more two varieties of herbicide (glufosinate) tolerant GM soybeans from Aventis for human food use: Liberty Link varieties A2704-12 and A5547-127. These varieties were already approved in the US (1998) and Canada (2000) (Source: <http://www.s.affrc.go.jp/docs/sentan/guide/evelop.htm>).

#### **3.2 United States**

Two further GM crop varieties have been approved for use in human food and animal feed by the US FDA:

- Insect resistant cotton Bollgard II 15985 (Cry2ab, Cry1ac) from Monsanto (July 2002)
- Glyphosate tolerant rapeseed canola GT200 from Monsanto (September 2002)

#### **3.3 European Union**

Despite the moratorium on approvals of new GM foods in the EU, the Commission has circulated a December 2002 notification to member states that assessments of two Monsanto GM cottonseed oils by the UK Advisory Committee on Novel Foods and Processes are substantially equivalent and they will be placed on the market. The cottonseed oils are derived from Roundup Ready and Ingard GM cotton varieties (Source: Press release 19 December 2002 via AgNet).

### **3.4 Biotechnology company changes**

In company news, during August 2002 the Monsanto company was spun off as a separate company again after its current owner, Pharmacia, was acquired by Pfizer, the world's largest pharmaceutical company. In September 2002 Bayer purchased Aventis.

## **4 LEGISLATIVE POSITION OF OVERSEAS GOVERNMENTS REGARDING GENETICALLY MODIFIED FOODS**

### **4.1 Food Use Approvals**

#### **4.1.1 US assessment of GM crops prior to field trials**

In August 2002 the US FDA published in the Federal Register a proposal under which new GM crops intended for field trials (approved by the USDA) would undergo a voluntary assessment of the suitability for the crop for human food or animal feed use. The rationale is that some of these crops might find their way into food or feed, through cross pollination or accidental mixing of seed, and a pre-assessment of possible effects could prevent health concerns or food recalls. Such an assessment might also prevent rejection of export shipments due to the presence of small amounts of GM crops not yet approved in overseas countries.

These assessments would not replace the full mandatory assessment of new crops prior to commercialisation by the FDA (and EPA). The Biotechnology Industry Organisation, an industry group, welcomed the proposal, saying that they would consider it a mandatory, rather than voluntary requirement (Source: New York Times 2 August 2002 via AgNet).

The proposal may be found at:

<http://www.ostp.gov/html/redregbio.html>

#### **4.1.2 USDA support for export commodities**

The USDA currently supports the export of commodities such as corn and soy through a number of measures that are related to potential GM content. One such measure is the development of sampling guidelines, and performance verification of test kits for GM crops. These are then used by US exporting companies to assure the status of their shipments.

The USDA announced in August 2002 a proposal for a new voluntary federal programme that US companies can use, where the Department will review the company's system for segregating GM crops at all levels in the food chain – from farm harvesting equipment to storage bins to processing plants. Federal inspectors will review the system and verify that minimum requirements were being followed. The system will be similar to that used for federal inspection of the meat industry. The system would be certified and monitored for compliance through routine documentation reviews and internal audits.

The proposal in the Federal Register may be seen at:

<http://www.usda.gov/gipsa/rulemaking/fr02/080602.pdf>

Further information is available from:

<http://www.usda.gov/gipsa/programsfgis/inspwgh/processver/processsv.pdf>

### 4.1.3 Animal Biotechnology

#### 4.1.3.1 *US: National Academy of Sciences*

In 2001 the US FDA Centre for Veterinary Medicine commissioned the National Academy of Sciences to convene an *ad hoc* committee of experts to identify science based risks and concerns associated with animal biotechnology (including cloning technologies) prior to a regulatory review of the food and environmental safety of these products. The results of the deliberations of this committee have been published as a book:

<http://www.nap.edu/books/0309084393/html/>

The risks and concerns associated with food safety in this book were similar to those considered in safety assessments of material derived from GM plants i.e. expression of transgenes, allergenicity, altered nutrition, etc. The report considered that the available evidence suggests that genetically engineered animals, including cattle, pigs, and fish, are probably safe to eat, but it would be wise to prevent them from escaping captivity, reproducing and possibly spreading their genes into wild relatives or other species. The Committee also felt that the regulatory framework may not be adequate to deal with animal biotechnology.

The cloning technologies of embryo splitting and nuclear transfer have already been used to produce some 1,400 Holstein dairy cows and the milk from these animals did enter the US food supply. However, intensive studies of the composition of milk or meat from cloned animals are lacking. The Committee felt that there were no evidence that food products from adult somatic cell clones or their progeny presented a food safety concern, but compositional studies should be performed.

#### 4.1.3.2 *UK: Agriculture and Environment Biotechnology Commission (AEBC)*

A September 2002 report by the AEBC called “Animals and Biotechnology” included a number of recommendations, the first of which was that the UK government set up a new advisory body to consider issues related to GM farm animals. Other food safety related recommendations were that post-commercialisation monitoring should be planned to look for unexpected welfare or health problems, and arrangements should be made to maintain consumer choice about whether to purchase such products. These recommendations would require labelling and segregation in production.

The full report is available from:

[http://www.aebc.gov.uk/aebc/animals\\_and\\_biotechnology\\_report.pdf](http://www.aebc.gov.uk/aebc/animals_and_biotechnology_report.pdf)

### 4.1.4 FDA assessments criticised

The Center for Science in the Public Interest (CSPI), described as a moderate Washington based group with respect to GM foods, has issued a report (7 January 2003) that criticises the

FDA assessment of the safety of GM foods before market release. Although such assessments are voluntary, all of the GM crops currently in the US food supply have been assessed by the FDA. The CSPI obtained 14 submissions under the Freedom of Information Act and found that in some cases biotechnology companies had refused some FDA requests for further information, and there were technical shortcomings and errors in some of the safety data. The report found that one GM developer used inadequate methodology to test for allergens, and others failed to evaluate toxicants and anti-nutrients.

It was pointed out that many of the applications assessed were for foods that never finally made it onto the market, but nevertheless they had been through the entire FDA process. The CSPI recommended that such assessments be made mandatory (this move is already in progress) and that the FDA develop safety testing guidelines to tell biotechnology companies the correct tests and procedures to use.

The press release and report can be obtained from:

<http://www.cspinet.org/new/200301071.html>

#### 4.1.5 GM crops as food aid in Africa

During the past few months the use of GM crops as food aid in Africa has been enormously controversial and the subject of much commentary. The controversy centres around two potential problems: (1) the potential human health effects of GM foods and (2) the potential effect on corn or meat exports to Europe if some of the GM seed is diverted into agriculture or used as feed for animals (Source: The Daily News Harare 17 June 2002 via AgNet). In July, Zimbabwe rejected a shipment of US corn on the grounds that unless it was milled, some could be used for planting, which would then jeopardise exports. The corn was then milled and accepted (Source: AlertNet 19 July 2002 via AgNet). Other countries facing famine but with concerns about GM material in food aid are Lesotho, Mozambique, Swaziland, Zambia and Malawi. Namibia has also refused GM yellow corn from South Africa fearing cross pollination with local corn (Source: Reuters 31 July 2002 via AgNet).

In August, Zimbabwean authorities reversed their decision and decided to accept 17,500 tons of corn from the US (Source: The Daily Telegraph 2 August 2002 via AgNet). However, the arrangement involved transfer of the US derived corn to the Zimbabwean government, who would then transfer the same amount of local corn reserves to non-governmental organisations for distribution to the community (Source: Washington Post 10 August via AgNet).

A meeting of affected countries was called by the United Nations World Food Programme in Johannesburg in August and this resolved the concerns of all the affected countries except Zambia (Agence France Presse 23 August 2002 via AgNet). Following a trip to South Africa, the US, and Europe to look at the issue of safety, Zambian scientists recommended that the government continue to refuse GM corn as food aid, and this decision was reaffirmed in October 2002 (Source: Associated Press 29 October 2002). Despite pressure from a number of sources, the Zambian government maintained its position, and in December 2002 the US provided Zambia with 30,000 tonnes of two non-modified grain crops (sorghum and wheat) as food aid (Source: Reuters 6 December 2002 via AgNet). At the same time 18,000

tonnes of GM corn food aid was removed from Zambia by the United Nations (Source: Financial Times 10 December 2002 via AgNet).

#### 4.1.6 EU approvals

On October 17 2002 EU Directive 2001/18/EC came into force, replacing Directive 90/220/EEC. The new Directive strengthens the pre-market assessment of new GMOs, and allows for post-market monitoring and general surveillance. The legislation had been adopted in February 2001 by the European Parliament, and national governments then had 18 months to incorporate the Directive into national law (Source: Europa 17 October 2002 via AgNet). Despite the adoption of the new Directive, the *de facto* moratorium on new approvals of GM crops for food use remained in place, as several EU member states refused to accept them until new labelling and traceability laws were adopted (see Section 4.2).

In July 2002 the Scientific Steering Committee of the European Commission issued a preliminary guidance document on the information needed for the risk assessment of genetically modified plants and derived food and feed. The document is intended to be a guide for notifiers seeking approval for commercial release as well as food and feed use of genetically modified crop plants. Thus it covers information relevant to agricultural and environmental effects, as well as human health. The full document is available at:

[http://europa.eu.int/comm/food/fs/sc/ssc/guidance\\_gmo\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/ssc/guidance_gmo_en.pdf)

#### 4.1.7 Korea

The Korean Food and Drug Administration has approved importation of MON810 and GA21 GM corn varieties for human food use, adding to the Roundup Ready soybean import approval granted in June 2000. Seven other varieties of GM crops are still being evaluated (Source: Asia Pulse 23 September 2002).

## 4.2 **Labelling**

### 4.2.1 EU labelling

In June 2002 the Environment Committee of the European Parliament approved a proposal to lower the threshold for mandatory labelling from 1% to 0.5% per ingredient. The Committee also voted on a proposal to require labelling of highly refined products such as oils and sugars (which cannot currently be tested for GM origins) as well as meat and dairy products from animals fed on GM feed. This will require extensive traceability throughout the food chain, as such products cannot be tested for GM content.

This legislation had been first introduced in July 2001 (see September 2001 report from this project) and consists of two proposals:

1. For traceability of GMOs throughout the food chain and products produced from GMOs

(See: [http://europa.eu.int/comm/food/fs/biotech/biotech09\\_en.pdf](http://europa.eu.int/comm/food/fs/biotech/biotech09_en.pdf))

## 2. Regulation of food and feed

(See: [http://europa.eu.int/comm/food/fs/biotech/biotech08\\_en.pdf](http://europa.eu.int/comm/food/fs/biotech/biotech08_en.pdf))

A useful overview of the proposed legislation has been published:

[http://www.bio-scope.org/disp\\_info\\_doc.cfm?id=62,9](http://www.bio-scope.org/disp_info_doc.cfm?id=62,9)

The proposed measures were to be discussed by the European Parliament plenary in July and then sent back to the EU Commission and individual governments for review, followed by final approval by the European Parliament (Source: Crop Biotech Update 21 June 2002 via AgNet).

In July 2002 the European Parliament by a narrow majority approved the first reading of the two proposals, but with some amendments. The proposal to label meat, milk and eggs obtained from animals fed on GM feed was rejected. However, the labelling of all GM food and feed irrespective of the presence of transgenic DNA or protein was supported (Source: EU press release 3 July 2002 via AgNet).

The proposals then went to the European Council of Ministers for approval, and it was hoped that agreement there would allow a resumption of approvals for GM crops (a *de facto* moratorium has been in place since June 1999). However, the October 2002 meeting of the EU Agriculture Ministers failed to agree on the measures proposed, particularly the threshold level of GM material for food labelling, and the tolerance level of accidental presence of GM seed in seeds for planting (Source: Associated Press 14 October 2002 via AgNet).

A later meeting of EU Agriculture Ministers in November 2002 did achieve agreement on further labelling requirements for GMOs. The agreement was claimed to establish a sound EU system to regulate the placing on the market and labelling of food and feed products from GMOs, and pave the way for the adoption of the traceability and labelling proposal in the Environment Council in December.

The compromise agreement will require the labelling of all GM derived food and feed, regardless of the presence of novel DNA or protein. A compromise was reached on the threshold level of GM above which labelling is required – instead of lowering it to 0.5%, a level of 0.9% was agreed. The level for adventitious contamination of seed by unauthorised GM material was set at 0.5%, provided the GM material had received a favorable EU scientific risk assessment. This measure will apply initially for 3 years, but may be extended (Sources: European Commission 29 November 2002 and Associated Press 28 November 2002 via AgNet).

The Environment Council meeting in December did support the traceability and labelling proposal, and so both draft agreements will now be sent to the European Parliament for further consideration.

Enzymes used in food production, such as chymosin, are exempt from labelling, even though they might be derived from GM bacteria. This was seen by US exporters as favouring European produced products such as cheese, over imported corn and soy.

A background article on EU-US trade and potential effects of GM food regulations has been posted by the Pew Initiative on Food and Biotechnology.

(<http://pewagbiotech.org/resources/issuebriefs/europe.pdf>).

#### 4.2.2 Labelling proposals in US states

Despite the Federal government's refusal to introduce labelling for GM foods, a number of individual states are considering legislation on the issue. Massachusetts, California, Maine, Michigan, Pennsylvania and Vermont are all considering such laws (Source: Worcester Telegram and Gazette 16 June 2002 via AgNet).

The state that came closest to introducing labelling rules was Oregon, where a petition gathered enough signatures to have the issue included on the state wide representative election ballot in November (Source: The Associated Press 25 June 2002 via AgNet). The labelling proposal was called Measure 27, and would have required labelling of all GM derived materials, including those that did not contain modified DNA or protein (Oregon Statesman 8 October 2002 via AgNet). Surprisingly, a federal agency, the FDA, sent a letter to the Governor of Oregon warning that the labelling measure could interfere with national marketing of food products (Source: USA Today 9 October 2002 via AgNet). After extensive lobbying by both sides, the Measure was rejected on November 5, by 73% of voters (Source: Reuters 5 November 2002 via AgNet).

#### 4.2.3 Foods in Australia

An article in a newspaper in Australia has referred to two products being labelled as containing material from GM plants: a Woolworths doughnut and a can of Spam. As in New Zealand, most Australian food products are silent on labelling, although some claim to be GM free (Source; The Advertiser 24 June 2002 via AgNet).

#### 4.2.4 Canada

In June 2002 the Canadian Standing Committee on Agriculture and Agri-Food released a report on "Labelling of Genetically Modified Food and Its Impacts On Farmers". It recommended continuation of the development of a voluntary labelling policy, a public information campaign to publicise the results of research into benefits and risks, assessment of the costs of segregation, and assessment of the trade implications of mandatory versus voluntary labelling.

The response by the Canadian government to the recommendations in the report was released in November 2002 (see: [http://www.agr.gc.ca/cb/biotech/gm\\_e.phtml](http://www.agr.gc.ca/cb/biotech/gm_e.phtml)). Reference was made to the voluntary labelling standard being developed by the Canadian General Standards Board, and expected to be approved and published in early 2003. A model to assess segregation costs is being developed by a team of Canadian academics and is also expected to be completed by early 2003.

The Canadian Biotechnology Advisory Committee released a report entitled “The Regulation of Genetically Modified Foods” in August 2002. This independent advisory committee provides advice to the Canadian government. The key finding of the report was that mandatory labelling of GM foods should not be implemented, due to concerns about cost and trade disputes. Instead the committee said a voluntary system should be implemented for at least five years, but only after an “agreed upon standard” for GM content can be established. One of the 20 committee members disagreed with the recommendation however, preferring a mandatory system instead.

See the complete report at: <http://www.cabc-cccb.ca>

#### 4.2.5 Japan

A survey of tofu and natto soybean products sold under organic food labels in Japan has found that 30% (of 76 samples) contain GM soy. The survey was conducted by the Japanese Farm Ministry, and such products contravene Japanese Agricultural Standards Rules (Source: Associated Press 28 August 2002 via AgNet).

In September 2002 Japan announced that it had found GM papaya amongst a papaya shipment from the US. The virus resistant GM papaya is principally grown in Hawaii, and was approved for human food use by the FDA in 1997, but has yet to be approved in Japan (Source: Jiji Press 18 September 2002 via AgNet).

#### 4.2.6 Russia

Russia apparently introduced mandatory labelling of GM foods in September 2002 but few details are available (Source: Food and Agricultural Report 4 September 2002 via AgNet).

#### 4.2.7 Switzerland

The Swiss House of Representatives voted on a variety of legislation related to biotechnology in October 2002. A moratorium on commercial planting of GM crops in Switzerland was rejected, but labelling and liability laws for GM food were supported. The legislation now proceeds to the Swiss Senate for further debate (Source: SwissInfo 3 October 2002 via AgNet).

## 5 CURRENT DEVELOPMENTS

### 5.1 Resources

#### 5.1.1 Council for Agricultural Science and Technology (CAST)

In June, this US based organisation released a review of the scientific literature comparing the environmental impacts of biotechnology derived and traditional crops. The report claims that soil, air and water quality all benefit from responsible use of current biotechnology derived soybean, corn and cotton crops. The report is available from:

<http://www.cast-science.org/biotechnology/index.html#biotechcropsbenefit>

#### 5.1.2 USDA Economic Research Service

This organisation produced a report in May 2002 that describes adoption of biotechnology derived crops in the US, and their economic and environmental effects. The analysis echoes other recent reports, which suggest that economic benefits are not always clear-cut, but farmer adoption of the technology for reasons of ease of use and simplicity of farm operation provide other advantages. The full report is available at:

<http://www.ers.usda.gov/publications/aer810/>

#### 5.1.3 Questions and Answers on the regulation of GMOs in the EU

A fact sheet on GMOs in the EU has been posted by the European Commission and is available via:

[http://europa.eu.int/comm/food/fs/gmo/gmo\\_index\\_en.html](http://europa.eu.int/comm/food/fs/gmo/gmo_index_en.html)

The fact sheet includes an overview of GM crops currently approved for food use in the EU.

#### 5.1.4 FAO website for biotechnology policy documents

The Food and Agriculture Organisation of the United Nations has created a website specifically for biotechnology documents of member countries (including New Zealand). The documents cover all aspects of biotechnology and not just agricultural uses. The website is at:

<http://www.fao.org/biotech/country.asp>

#### 5.1.5 Environmental Biosafety Research

This is the title of a new journal devoted to scientific research in the area of GMO biosafety. Website: <http://www.edpsciences.org/journal/index.cfm?edpsname=ebr>

#### 5.1.6 Report by the UK Soil Association

In August 2002 a report entitled “Seeds of Doubt” was released by the UK Soil Association. This report challenged the claims of economic and environmental benefits from GM crops. The summary states: “The evidence we have gathered demonstrates that GM food crops are far from a success story. In complete contrast to the impression given by the biotechnology industry, it is clear that they have not realised most of the claimed benefits and have been a practical and economic disaster. Widespread GM contamination has severely disrupted GM-free production including organic farming, destroyed trade and undermined the competitiveness of North American agriculture overall. GM crops have also increased the reliance of farmers on herbicides and led to many legal problems.”

A summary and the full report can be obtained from:

<http://www.soilassociation.org/gm>

The claims in this report have been criticised by a number of authors, including a detailed response from a Canadian perspective at:

[http://131.104.232.9/agnet/2002/10-2002/agnet\\_october\\_3.htm](http://131.104.232.9/agnet/2002/10-2002/agnet_october_3.htm)

#### 5.1.7 Essential Biosafety Edition 2

The second edition of this CD ROM resource was released in November 2002. It includes information about safety and regulation of GM crops internationally, with a searchable library of publications on the topic. See:

<http://www.essentialbiosafety.info>

#### 5.1.8 World Bank biotechnology assessment

The World Bank has initiated an consultative assessment on agricultural science and technology, including biotechnology.

From their website: “An international assessment on agricultural science and technology would bring together representatives from governments, industry, the scientific community and NGOs from around the world to work together to give decision makers the tools and information they need to answer these questions in a larger policy context and to shape the future of agriculture. International assessments have proven invaluable for guiding policy makers on the key questions of our time, in a way that brings the singular insights of scientists, advocacy groups and industry specialists to bear on complex scientific, economic and political concerns.”

Further information available from:

<http://www.agassessment.org/>

### 5.1.9 Biosafety in Asia and Africa

The United Nations Industrial Development Organisation Regional Office in Thailand has published a report on “Biosafety Policy Options and Capacity Building Related To Genetically Modified Organisms in the Food Processing Industry of ASEAN”. Part of the report provides an overview of the status of biosafety regulatory systems, trade and biotechnology activity in a number of Asian countries. The full report can be downloaded from:

[http://www.isaaa.org/kc/Global\\_Status/global/Biosafety/biosafemenu.htm](http://www.isaaa.org/kc/Global_Status/global/Biosafety/biosafemenu.htm)

A similar (but much shorter) review from an African perspective has been published at:

<http://www.agbiotech.net/reviews/dec02/pdf/abn102.pdf>

## 5.2 **Human Health**

### 5.2.1 Risk of transfer of genes from GM food to bacteria in the human gut

The results from a series of five related research projects funded by the UK Food Standards Agency (FSA) investigating the transfer and survival of DNA from GM crops into the bacteria of the human gut were released in July 2002. The press release stated:

“The most recently completed study - which will be published in a scientific journal later this year - shows that in real-life conditions with human volunteers, no GM material survived the passage through the entire human digestive tract. Although some DNA survived in laboratory-created environments that simulated human or animal gastrointestinal tracts, the research concluded that the likelihood of functioning DNA being taken up by bacteria in the human or animal gut is extremely low. “

In summary the research projects covered the areas of:

- *Survival of ingested DNA in the gut and the potential for transfer to resident bacteria.*  
Survival of naked DNA was studied *in vivo* in the human mouth and after passage through the gut. The ability of naked DNA to transfer to gut bacteria was investigated *in vitro*, and *in vivo* in rats. The researchers concluded that there is a possibility of rare acquisition of GM sequences by resident bacteria in the mouth or gut. However, the probability of such events is influenced by the GM constructs as it depends largely on the presence of matching sequences in the GM DNA and the recipient bacterium. It was stressed that the significance of such transfers must be taken within evolutionary context as humans have consumed huge amounts of DNA in food throughout evolutionary history and the possibility of gene acquisition by resident oral and gut bacteria has always existed.
- *Evaluation of the risks associated with using GMOs in human food.*

Research projects in this area were designed to evaluate whether there is a significant risk that genetically modified plants and bacteria can transfer genetic material to other organisms within the gastrointestinal tract of humans. Studies looked at:

- (i) The capacity of transgenic DNA derived from genetically modified soy and maize to persist in the human intestinal tract *in vitro* and, in the case of soy, *in vivo*.

*In vitro* studies showed that 80% of the transgene from naked GM soy DNA was degraded in gastric simulations, whereas when the DNA was in the presence of various other food components the rate of degradation decreased. These data indicated that some transgenes in GM food may survive passage through the small intestine.

*In vivo* studies involved feeding a meal containing commercially available GM soy to human volunteers. The survival of the ingested DNA was determined after passage through the small intestine of volunteers with an ileostomy and through the complete digestive system of volunteers with intact gastrointestinal tracts. Results indicated that transgenes from GM soy did survive passage through the small intestine but appeared to be completely degraded in the human colon. Although there was some evidence of gene transfer from GM soy to intestinal microflora in the small bowel, the microbial population containing plant-derived DNA was an extremely minor component of the intestinal population. As no evidence of a similar transfer was found after passage of the DNA through the intact digestive system it was suggested that it is possible that ileostomists may have an altered gut physiology which could influence such gene transfer events.

- (ii) The potential for vertical transfer of genetic material from bacteria to mammalian gut epithelial cells.

Intestinal epithelial cell lines were used *in vitro* to study the potential for gene transfer from GM plants either directly or via the intestinal microflora. Data indicated that such transfers are unlikely to occur.

- *Assessment of the risks of transfer of antibiotic resistance from transgenic plants to micro-organisms and the potential for spread of GM DNA and antibiotic resistance genes via rumen micro-organisms*

The ability of a transgenic antibiotic resistance genes to be released from the plant DNA and to be taken up and confer resistance to gut organisms was studied *in vitro* in rumen fluid and *in vivo* in chickens and sheep. Results concluded that whilst the antibiotic resistance gene was stably incorporated into the plant DNA the DNA can be released from the plant during digestion and may become available to transfer to micro-organisms. Survival of biologically active DNA in rumen fluid, in the crop and gut of chickens and in the anaerobic conditions of silage effluent was poor suggesting little likelihood of antibiotic resistance being acquired by microbes in these environments. It was, however, shown that biologically active DNA from plants can survive in the oral cavity for long enough to transfer to microbes in this site, implying that DNA released from the diet within the mouth may retain sufficient biological activity for the transformation of any competent oral bacteria.

Detailed reports for each research project are available at:

[http://www.food.gov.uk/science/sciencetopics/gmfoods/gm\\_reports](http://www.food.gov.uk/science/sciencetopics/gmfoods/gm_reports)

A discussion document rejecting the interpretation of the results by the UK FSA has been published by the Isis organisation at:

<http://www.i-sis.org.uk/hgthumangut.php>

### 5.2.2 Assessment of allergenicity of GM crops

A useful overview of the status and possible future developments in the assessment of allergenicity has been published (Kimber and Dearman, 2002). In particular the article examines the current status of animal based models.

### 5.2.3 New GM crops with properties relevant to human health

#### 5.2.3.1 *Soybeans with reduced allergenicity*

The Agricultural Research Service of the USDA has been developing a soybean which contains lower amounts of one of the known soybean allergens, a protein known as P34. Using a gene silencing technique they developed a variety which has been undergoing field trials since 2001; so far yields and properties have been the same as traditional soybeans. Feeding trials, as well as skin prick tests on new-born piglets have commenced (Source: <http://www.ars.usda.gov/is/AR/archive/sep02/soy0902.htm>).

#### 5.2.3.2 *Enhancing nutrition using biotechnology*

In June 2002 the Journal of the American College of Nutrition published a supplement devoted to the future of food and nutrition using biotechnology. The articles contain details of projects in development to improve the nutritional content of plant based foods, including the mineral and vitamin content, as well as altering the fatty acid composition of cooking oils. The contents list is available at:

[http://www.jacn.org/content/vol21/suppl\\_3/](http://www.jacn.org/content/vol21/suppl_3/)

#### 5.2.3.3 *Sugar cane*

Cuba has been experiencing markedly reduced incomes from sugar exports for several years. In an effort to develop an innovative product, Cuban scientists are in the process of introducing genes from a bacterium that produces fructose into sugarcane, which produces only sucrose. Fructose is less fattening than sucrose, and twice as sweet. Consequently fructose is used in many products such as soft drinks. Cuba has taken out a US patent on the technology (Source: Associated Press 13 December 2002 via AgNet).

#### 5.2.4 Unintended effects

Some recent debate has explored the issue of unintended effects of gene transfer. The potential for such effects forms an important part of the safety assessment process for new GM foods. An article in the October issue of *Nature Biotechnology* (Schubert, 2002) offered several concerns:

- The potential for post-translational modifications of novel expressed proteins to differ in the host and source organisms;
- The potential for foreign genes to evoke the synthesis of unexpected, and potentially toxic molecules through perturbation of the gene expression pattern of the whole cell; and,
- The synthesis of unexpected or novel products through interaction with endogenous pathways.

Two responses were published in the December issue. One letter (Beachy *et al.*, 2002) pointed out that the three scenarios raised also occur with the random “natural” gene mutations and rearrangements that drive evolution. GM crops in development undergo a highly selective process that is unlikely to permit unintended or unexpected variation. The point is made that unintentional consequences are more likely to occur in nature than in biotechnology where more precise tools are used to achieve a specific goal. A second letter (Avery, 2002) asks why GM crops should be tested long term for such unintended effects when crops modified by intensive radiation or chemical mutagenesis are exempt.

These discussions cover material that has already been extensively debated elsewhere but are a useful summary.

### 5.3 **Consumer Issues**

#### 5.3.1 Debate on genetically modified foods in the United Kingdom

The Agriculture and Environment Biotechnology Commission was set up in June 2000 with a remit to provide the UK Government and Devolved Administrations with independent, strategic advice on developments in biotechnology and their implications for agriculture and the environment. It looks at the broad picture taking ethical and social issues into account as well as the science.

In July 2002 the Commission was charged with undertaking a national public dialogue on genetically modified crops, prior to their commercial release. The suggestion that there should be a national debate stemmed from the report "Crops on Trial" published by the Agriculture and Environment Biotechnology Commission (AEBC) in September 2001.

The debate was launched in September 2002 and has three main parts: a science review, a public debate and an economics study. It will report back to the government in June 2003. Further details are available from the website:

<http://www.gmpublicdebate.org/>

### 5.3.2 Starlink update

Since the major activity involving recalls and testing for Starlink corn during 2000, discoveries of Starlink in corn have declined. In October 2002 an overview announced that no Starlink had been found in food products since 2000-2001. Japan had not detected Starlink in a corn shipment since May 2001, and the Japanese Starch and Sweeteners Industry Association had dropped its supply of identity preserved non-biotech corn to its customers (due to higher costs). The US market share of Japanese corn imports dropped from 90% in 2000 to 50% in 2001 but returned to close to 90% in 2002 (Sources: DirectAg 11 October 2002 and Knight-Ridder Tribune 21 October 2002 via AgNet).

The Canadian Food Inspection Agency has been monitoring corn shipments from the US since late 2000, both by examining accompanying documentation and testing of samples. Between July and September 2002 two rail shipments (out of hundreds of samples) were rejected for the detection of trace quantities of Starlink (Source: Canadian Food Inspection Agency press release October 2002 via AgNet).

After these reports it was a surprise when Japan announced on 27 December 2002 that it had found trace amounts of Starlink in a shipment of US corn (Source: Reuters 30 December 2002 via AgNet). The discovery concerned about 1,200 tonnes of a 19,000 tonne shipment, and was the first such detection since Japan instituted its own testing programme in 2000. Following the discovery, Japan increased the proportion of imported corn shipments that would be subject to testing for Starlink from 5% to 50% (Source: Reuters 6 January 2003 via AgNet). The Starlink discovery was also a surprise for the USDA Grain Inspection, Packers and Stockyards Administration (GIPSA), which reported that the buyer's and seller's contracts indicated that the grain had been tested for Starlink prior to export, and found it negative. GIPSA said it was working with the Japanese authorities to clarify the situation (Agweb.com 7 January 2003 via AgNet). Despite the discovery, US corn exports to Japan were not affected (Source: Dow Jones 8 January 2003 via AgNet).

### 5.3.3 Corn imports into Australia

Due to the serious drought in Australia, in January 2003 it has taken the unusual step of importing corn to be used as poultry feed. Some of the corn comes from the US and is likely to contain GM material. A 48,000 tonne shipment from the US will be processed to prevent the possible spread of GM corn in Australia. The corn will be milled, steamed and made into pellets in a high security process to prevent any GM seed germinating. The Australian regulatory authorities also stressed that there was no evidence that GM content of feed could pass on to poultry (Sydney Morning Herald 9 January 2003 via AgNet).

### 5.3.4 Consumer acceptance of GM foods

The large number of consumer surveys about GM foods are generally not covered in this report. However, a recent research report (Lusk and Sullivan, 2002) does provide a review of research in the area, in addition to the results of a US survey, which suggested that consumer attitudes to GM vary markedly according to the attributes or purposes of the modification.

A more extensive review of surveys of public perceptions of biotechnology has been published in the Journal of Food Science (Blaine *et al.*, 2002).

### 5.3.5 Possible contamination of soybeans with corn modified to produce pharmaceuticals

In November 2002 the FDA announced that it had ordered Prodigene (see Section 5.1.6.3) to destroy 500,000 bushels of soybeans rather than sell them for food because they were contaminated with GM corn once grown in the same field. None of the soybeans entered the food supply.

The soybeans were grown in fields in Nebraska and Iowa, in which a GM corn modified to produce a pharmaceutical (the identity of which has not been disclosed) had been grown. That corn crop had been unsuccessful and so the field was ploughed and replanted with (non-GM) soy. During the soy harvest Prodigene noticed that a few stalks of “volunteer” corn (leftover seeds from previous crops) were mixed in with the soy – an estimated 65 grams of stalks were mixed with about 500 bushels of soy, which then became mixed with a further 500,000 bushels of soy. Agriculture Department inspectors present during the harvest notified the FDA. The soy was estimated to be worth approximately \$2.7 million.

Prodigene were at risk of prosecution as it was determined that they had not properly destroyed the corn crops as required by their field trial permits. The Grocery Manufacturers of America cited the incident as support for their concern about the use of food crops for the development of plant-made pharmaceuticals. Non food crops such as tobacco were recommended as an alternative (Source: GMA press release 14 November 2002 via AgNet).

It later emerged that USDA inspectors had noticed the volunteer corn prior to harvest but the Nebraska farmer had failed comply with instructions to remove it (Source: Knight Ridder Tribune 14 November 2002 via AgNet). The volunteer corn was also found to have not been detasseled, prompting fears about cross-pollination. In Iowa, these fears prompted the USDA to order 155 acres of surrounding corn to be pulled up and incinerated (Source: Washington Post 14 November 2002 via AgNet).

The USDA ordered Prodigene to pay \$3 million in penalties in December 2002, including \$2.7 million for the disposal of the contaminated soy plus \$300,000 as a fine for violating the Plant Protection Act (Source: Associated Press 6 December 2002 via AgNet).

This action by the USDA was followed shortly after by the imposition of a fine of \$8,800 on Dow AgroSciences for a failure to plant appropriate buffers of trees and corn to prevent gene transfer from an experimental corn plot in Hawaii (Source: Washington Post 13 December 2002).

## 5.4 **Agricultural and Environmental Issues**

### 5.4.1 GM wheat

Wheat is the only major commodity crop for which GM varieties are not commercially grown. During December 2002 Monsanto Canada lodged an application with the Canadian Food Inspection Agency to allow commercial release of Roundup Ready wheat, as well as its

use as animal feed. This joins an application already lodged with Health Canada to allow the crop to be used for human food. Commercialisation of GM wheat is not expected before 2005 at the earliest (Source: Globe and Mail 8 January 2003 via AgNet).

#### 5.4.2 Canola containment

A publication from Australia's Cooperative Research Centre for Australian Weed Management (Reigler *et al.*, 2002) in June 2002 described measurement of pollen flow from a herbicide tolerant canola variety. The variety was classically bred to be resistant to imidazolinones and other acetolactate synthase inhibitors. Crosses to any conventional canola variety would produce a resistant seed.

The study involving the collection of more than 48 million seeds from 63 fields across southern Australia. It showed that pollen was carried to other fields in amounts well below internationally recognised levels for unwanted genetic transfer. The amounts were so small that it would be almost impossible to detect the gene flow using current DNA assessment methods. State and local governments across Australia are debating proposals to set up GM-free zones to address concerns from some farmers that cross-pollination from GM crops could limit their ability to market in Australia and overseas. The most immediate concern is GM canola, with applications for its commercial release already filed with the Commonwealth Government. The results are considered to have major implications for GM crops since the pollen spreads exactly the same way, mostly by wind or insects. Samples were taken from locations as close as the next field and ranging up to five kilometres away. The furthest distance any cross pollination was detected was 2.6 kilometres. It was found that on average only nine seeds in 100 000 carried the new gene. The very highest occurrence found was seven seeds in 10 000. The authors stated that "A key implication of this finding is that non-GM Australian canola is not in any danger of being excluded from markets on the basis of containing unwanted genes. We were only able to detect pollen flow by growing 48 million seedlings and testing each plant for resistance. Our data indicates that gene flow is so low that any practicable tests would not be able to detect pollination from GM canola in non-GM crops".

The research supported recent findings in Canada that showed very little movement of GM genes between canola crops. To assess gene flow, seeds were collected from conventional canola fields growing near herbicide-resistant fields in New South Wales, Victoria and South Australia. Parallel studies were undertaken in Western Australia, with the same general results. At least 100,000 seeds were taken from each of three locations in each field of conventional canola. To determine whether pollen flow from resistant sources to susceptible fields had occurred, the seeds were planted, seedlings treated with herbicide, and any survivors confirmed as resistant (Source: Press release 28 June 2002 via AgNet).

#### 5.4.3 Rapeseed/canola field scale releases monitoring report form UK

In December 2002 the UK Department of Environment, Food and Rural Affairs released a report examining the flow of transgenes to crops and wild relatives from field trials of GM rapeseed/canola from 1994 to 2000. The full report is available from:

[www.defra.gov.uk/environment/gm/research/epg-1-5-84.htm](http://www.defra.gov.uk/environment/gm/research/epg-1-5-84.htm).

The main findings of the report include:

- Gene flow between GM and adjacent conventional oil seed rape crops

The occurrence of cross pollination decreased rapidly over a distance of a few metres but was detected at a levels of 0.5% at 250m at one site. Higher levels of out crossing were detected when the GM crops was grown near a varietally associated crop. The report concludes that "the results presented show different situations can give very different results under natural field conditions".

- Feral and Volunteer oilseed rape

The incidence of transgenic volunteers at sites was monitored for several (up to five) years. The number of volunteers that were detected was variable. In one incidence transgenic oil seed rape volunteers persisted until 2000 at least from a crop harvested in 1996. GM volunteers appear no more persistent than non-GM volunteers. A low level of gene flow was detected from GM oil seed rape to feral rape growing nearby (up to 20m). The report concludes that transgenes can persist in volunteers and feral populations but the level of occurrence is low and the transgenes did not appear to persist.

- Interspecific gene flow

Gene flow by cross pollination between GM oil seed rape and *Brassica rapa* was detected at a site where a small amount of *B. rapa* was deliberately sown alongside a GM crop, and at another site where GM oil seed rape was sown in an area where weedy *B. rapa* was a known problem. The report concludes that where *B. rapa* and oil seed rape (*B. napus*) are grown together, gene flow will occur. Cross-pollination between oil seed rape and other wild relatives was not detected.

The advice of the Advisory Committee on Releases to the Environment (ACRE) to the UK government is at:

<http://www.defra.gov.uk/environment/acre/advice/advice21.htm>

The advice concludes: "ACRE considered the results of the monitoring carefully. ACRE's risk assessment of GM oil seed rape has always assumed some gene-flow will occur and that this does not in itself constitute a risk to human health or the environment. It was concluded that the extent of gene flow observed in the monitoring between GM oil seed rape and adjacent crops, feral oil seed rape and wild relatives was entirely within expectations. The persistence of GM volunteers and feral oil seed rape plants were also entirely within expectations.

ACRE members were content that the results of the monitoring were consistent with the existing risk assessment and no further action was necessary. ACRE welcomed the immediate publication of the monitoring report."

#### 5.4.4 Gene flow reviews

The June 2002 issue of Nature Biotechnology included a number of articles related to the environmental impact of GM crops, particularly in terms of pollen based gene flow. These included reviews of:

- Liabilities and economics of transgenic crops (Smyth *et al.*, 2002);
- Potential for environmental impact of transgenic crops (Dale *et al.*, 2002);
- Excision of selectable marker genes from transgenic plants (Hare and Chua, 2002); and,
- Molecular strategies for gene containment in transgenic crops (Daniell, 2002).

#### 5.4.5 Commercial growing approvals in Australia

The Australian Office of the Gene Technology Regulator (OGTR) announced in June 2002 that it had received its first application to grow genetically modified canola on a commercial basis (Australia already allows the Ingard variety of GM cotton to be grown). The application comes from Monsanto. The OGTR was established in June 2001 to replace the previous voluntary arrangements that applied under the Genetic Manipulation Advisory Committee.

This canola application is in addition to approximately 20 applications to grow GM crops as limited or controlled field trials. The applications under consideration by OGTR include:

- GM Cotton: Five applications for field trials and two applications for commercial release of Bollgard II and Bollgard II/Roundup Ready cotton;
- GM Canola: Two applications for field trials and one for a commercial release;
- GM Oilseed poppies: Two applications for field trials;
- GM Sugarcane: One application for a field trial.

(Source: OGTR Media release 21 June 2002 via AgNet).

The GM sugarcane has been developed for the purpose of examining a new rapid tissue culture process, and is not intended for development as a food crop (OGTR Press release 5 November 2002 via AgNet).

In July 2002 Aventis Crop Science announced that it was also applying to the OGTR for approval to commercially release the InVigor hybrid canola (Source: Aventis Media Release 22 July 2002 via AgNet). Invigor is a hybrid which is herbicide (glufosinate or Liberty) tolerant.

In September 2002 the OGTR approved a geographically limited commercial release of Bollgard II and Bollgard II/Roundup Ready cotton. They may be planted below 22 degrees south latitude. Their planting in areas north of that line was rejected due to concerns about their potential to become a weed problem, although field trials may be allowed to gather data on this issue (Source: Dow Jones 24 September 2002 via AgNet).

Monsanto's insect resistant Ingard and Roundup Ready/Ingard cotton varieties have been grown in Australia for the past two years under a transitional approval under a previous voluntary system in Australia. With the expiry of that approval expected the OGTR

announced in November 2002 that it would be preparing comprehensive risk assessment and management plan for their commercial release (See: [www.ogtr.gov.au](http://www.ogtr.gov.au)).

#### 5.4.6 GM crop plantings internationally

##### 5.4.6.1 *International Service for the Acquisition of Agri-Biotech Applications (ISAAA) Annual Report*

The full ISAAA annual global review of commercialised transgenic crops for 2001 has now been published (see: [www.isaaa.org/](http://www.isaaa.org/)). The document gives an overview of GM crop use from 1996-2001, as well as an in depth look at Bt cotton, including data on agronomic, environmental, social and economic benefits.

##### 5.4.6.2 *China*

A report from Patrick Moore refuting the Greenpeace allegations that Bt cotton has been a failure in China, also contains the information that this variety of cotton has now been planted on over one million hectares (approximately 2.5 million acres) in northern China. This represents one third of the total area of cotton in this region (Source: National Post June 20 2002 via AgNet). Another estimate gives a total of 1.5 million hectares of GM cotton in China which represents 35% of the total cotton crop. Two thirds of the GM crop is said to be Monsanto developed traits (Source: Dow Jones 26 June 2002 via AgNet).

China plans to increase its spending on agricultural biotechnology research five times to \$US500 million annually by 2005, according to Fortune magazine. Challenges for the development of the sector include a lack of strong patent protection, with a shortage of venture capital (Source: ISAAA 22 November 2002 via AgNet).

##### 5.4.6.3 *United States*

The proportion of plantings of GM soy, corn and cotton by US farmers have increased between 2001 and 2002 according to a survey by the USDA published in June 2002. The number of acres of GM corn showed the biggest increase; from 26% to 34% of the total area planted. The GM soy planted area increased from 68% to 75% of the total crop and cotton from 69% to 71%. Overall, total soybean acreage decreased by 2%, the total corn acreage increased by 4%, and the total acreage of cotton decreased by 9% (Source: Illinois Agri-News 19 July 2002 via AgNet and <http://usda.mannlib.cornell.edu/reports/nassr/field/pcp-bba/acrg0602.txt>).

##### 5.4.6.4 *Ontario, Canada*

Estimates by AGCare (an Ontario based farmers organisation) are that GM crop plantings in the state rose in 2002: soybeans 40-50% of the total crop (25-30% in 2001), corn 45-50% (40% in 2001) and canola 90-95% (80% in 2001) (Source: Press release 1 August 2002 via AgNet).

#### 5.4.6.5 *Australia*

The GM proportion of the Australian cotton crop has been estimated by the CSIRO as 50% in 2002, with predictions that it will reach 100% in the future. Australia produces 700,000 tonnes of cotton lint a year, with almost all of it being exported (Source: Reuters 14 August 2002 via AgNet).

#### 5.4.6.6 *Vietnam*

A news report indicates that G49 corn from Syngenta (formerly Novartis) is being used in Vietnam (this is probably Event 176 or Bt11). It is unclear whether this is a commercial release, or extensive field trials (Source; Saigon Times 17 October 2002 via AgNet).

#### 5.4.6.7 *Spain*

Although only tiny amounts of GM crops are grown in Europe (principally field trials), a small amount of Bt corn is being grown commercially by small farmers in Spain. Approximately 50,000 acres of Bt corn has been grown every year since 1998 (representing 4% of the total Spanish corn crop) and the benefits have been detailed in a report available from:

[http://www.europabio.org/pages/ne\\_gbgmcrops.asp](http://www.europabio.org/pages/ne_gbgmcrops.asp)

#### 5.4.6.8 *South Africa*

Although white corn represents only around 3% of the US corn crop (the rest is yellow corn), white corn is more widely grown in South Africa. That country has been growing GM yellow corn for several years, but in 2002-2003 commercial plantings of GM white corn began. Approximately 7-8% of the white corn crop will be GM in 2003 (Source: Dow Jones 4 October 2002 via AgNet).

#### 5.4.6.9 *Brazil*

Brazil's rejection of GM soy has apparently adversely affected the Amazonian rain forest. It has been claimed that soy farmers are clearing rain forest in the north to plant soy, in order to avoid soy being planted in the south which is mixed with GM soy coming in from Argentina (Source: Reuters 5 November 2002 via AgNet).

#### 5.4.6.10 *India*

After approval for GM cotton (see below), the next GM crop expected to be approved for commercial release in India is a herbicide resistant mustard, developed by ProAgro, in collaboration with Aventis. One difficulty for approval is the extent of cross pollination; mustard is a crop that cross pollinates extensively, and there are concerns about it affecting wild relatives (Source: Financial Times 6 November 2002 via AgNet).

#### 5.4.6.11 *Pakistan and Bangladesh*

As well as India, Pakistan and Bangladesh are also major producers of cotton. The introduction of GM cotton into Bangladesh is currently hampered by the lack of a regulatory system to provide safety assessments and permits. Pakistan also is in the process of developing such a regulatory system, although the required legislation is still at a draft stage. In November 2002, the US and Pakistan announced a joint operating arrangement worth \$10M. The agreement will involve a natural sciences linkage programme (Source: International Service for the Acquisition of Agri-biotech Applications 8 November, 2002 via AgNet). Later in November Pakistan announced that it would lift a ban on the importation of GM seeds, which was seen as ineffective against smuggling, and introduce better regulation. The ban will be lifted on GM seed imports that have been deemed legal in the originating countries (Source: Asia Times Online 15 November 2002).

#### 5.4.6.12 *Philippines*

The Philippines Department of Agriculture has given approval for commercial planting of Monsanto's Yieldgard (MON810) insect (corn borer) protected corn in December 2002. This is the first commercial release of a GM crop in the Philippines (Source: Monsanto press release 5 December 2002 via AgNet).

#### 5.4.7 GM cotton performance in China

A further rebuttal of the Greenpeace report has been published by the director of one of the laboratories whose work was used as the basis for the report. The scientist, who was in the US when the report was originally published, reviewed the material on his return to China, and described the Greenpeace summary as incorrect and derived the opposite conclusion to what the work actually concluded (See:

<http://comet.sparklist.com/scripts/lyris.pl?visit=agbioview&id=199097191>).

#### 5.4.8 GM cotton performance in India

The Indian Genetic Engineering Approval Committee gave permission for commercial planting of three Bt cottonseed hybrids in March 2002. The varieties were developed by Monsanto in collaboration with an Indian company Mahyco, and have been planted in over 100,000 acres. However, assessment of the performance of the GM cotton has been hampered by complicating factors, such as drought, infection with leaf curl virus and root rot disease, and the failure of farmers to comply with technical specifications such as refugia management and planting conditions. Government sources and NGOs have disagreed on the economic value of the crop (Source: Nature Biotechnology November 2002; 20: 1069).

#### 5.4.9 GM crop development in Asia

Most of the attention for GM developments in Asia has been on the enormous development activity taking place in China. However, both Vietnam and Korea also have GM crop development programmes. The South Korean government announced in September 2002 that their Rural Development Administration had 50 types of GM crop in development (Source: Asia Pulse 11 September 2002 via AgNet). Vietnam also has an extensive development

programme, but is being held back by the lack of government statutes regulating biological safety (Source: Saigon Times Daily 6 September, 2002 via AgNet).

#### 5.4.10 New GM crops with properties relevant to agriculture

##### 5.4.10.1 *Groundnut*

The Hyderabad based International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) has announced that it has developed a GM groundnut (peanut) which has been engineered to confer resistance to the Indian peanut clump virus, which is widespread throughout India. This was achieved by incorporating the coat protein and polymerase genes from the virus into the nut, using the *Agrobacterium tumefaciens* vector. Two years of glasshouse trials are to be followed by two years of open field trials before commercial release (Source: Business Line 30 July 2002 via AgNet).

##### 5.4.10.2 *Salt tolerance*

China has announced the development of soybeans, rice and tomatoes which can tolerate high salt levels in soil. The crops were developed by using genes derived from the sequencing of Suaeda Salsa, a common plant found in saline soil in China. China has approximately 82 million acres of saline soil, and globally saline soil makes up about a quarter of the land area (Source: Agence France Presse 15 September 2002 via AgNet).

##### 5.4.10.3 *Rice bacterial blight*

The Philippine Rice Research Institute is expected to commercialise GM rice that is resistant to bacterial blight within three years. Field trials of the rice in Munoz showed good agronomic performance in 2001 (Source; Business World 16 September 2002 via AgNet).

##### 5.4.10.4 *Trehalose confers stress tolerance in rice (Garg et al., 2002)*

Scientists in the US and Korea have reported the effective expression of trehalose in rice. Trehalose is a disaccharide of glucose that stabilises biological structures under abiotic stress in bacteria, fungi, and invertebrates. With the notable exception of the desiccation-tolerant "resurrection plants," trehalose is not thought to accumulate to detectable levels in most plants. By using trehalose biosynthetic genes from *Escherichia coli* expression of trehalose in rice was achieved. Compared with nontransgenic rice, several independent transgenic lines exhibited sustained plant growth, less photo-oxidative damage, and more favorable mineral balance under salt, drought, and low-temperature stress conditions. Depending on growth conditions, the transgenic rice plants accumulate trehalose at levels 3-10 times that of the nontransgenic controls.

The authors of this paper have also announced their intention to place this technology in the public domain for use by resource poor parts of the world (Source: Cornell University News Service 25 November 2002 via AgNet).

#### 5.4.11 UK Field trials

The extensive field trials of GM crops in the United Kingdom were the subject of controversy in August 2002 when it was discovered that the rapeseed/canola trials in 1999, 2000 and 2001 had been contaminated with small quantities of another variety of seed (previously approved in the UK). The Department of Environment, Food and Rural Affairs announced that the variety contained an additional gene: an antibiotic resistance marker (nptII) making the plant resistant to neomycin and kanamycin, but did not pose any danger to public health. The company Aventis, who had developed the seed, may face prosecution (Source: Independent 16 August 2002 via AgNet). Planting of the intended 2002 trials was delayed while testing of the seeds intended to be used was conducted. They were declared free of contamination at the end of August 2002 and planting was commenced at 18 sites (Source: Reuters 30 August 2002 via AgNet).

### 5.5 **GM Animal Feed**

#### 5.5.1 Bio-Scope

A website resource on biotechnology called Bio-Scope has published a list of animal feeding trials comparing feed derived from GM crops with those from conventional sources. The list is organised according to animal and may be found at:

[http://www.bio-scope.org/disp\\_doc.cfm?id=9D55187FAB5D4C778195128CB93EE863](http://www.bio-scope.org/disp_doc.cfm?id=9D55187FAB5D4C778195128CB93EE863)

#### 5.5.2 Japanese use of GM crops as animal feed

Currently the Japanese Agriculture Ministry is responsible for ensuring the safety of animal feed and asks GMO suppliers to voluntarily undergo its safety assessments (32 GM varieties of 5 crops have already been approved – see: <http://www.s.affrc.go.jp/docs/sentan/guide/edevelp.htm>). From April 2003 these assessments will be mandatory, and the Ministry plans to also conduct testing of imported materials for unapproved GM varieties. In contrast to the Health Ministry, which has a zero tolerance for unapproved varieties, the Agriculture Ministry is considering allowing up to 1% unapproved GMOs in feed grains, provided the safety of the variety has already been confirmed by the originating country (Source: Reuters 10 October 2002 via AgNet).

#### 5.5.3 Herculex I as animal feed

A study at the Iowa State University has found that the newly approved Herculex I variety of corn that contains the Cry1F Bt protein is as wholesome and nutritious as traditional counterparts. The study was conducted in dairy cows. No differences were detected in dry matter intakes, efficiency of milk production, milk somatic cell counts and physical and blood indicators of cow health between the test and control feeding groups (Source: Crop Biotech December 5 2002 via AgNet).

## 5.6 Miscellaneous

### 5.6.1 Using GM plants to produce pharmaceuticals

During the period of this report, the issue of using of GM plants to produce pharmaceuticals and industrial chemicals has become increasingly prominent. The use of food crop plants for these purposes will have important implications for GM foods.

#### 5.6.1.1 *Overview*

A useful summary of the issues associated with the use of genetically modified plants to produce pharmaceuticals or industrial chemicals has been published at:

<http://www.aenews.wsu.edu/July02AENews/July02AENews.htm#PharmFarming>

Another review, concerning the production of antibodies in transgenic organisms, has also been published (Schillberg *et al.*, 2002).

#### 5.6.1.2 *Regulatory Oversight*

The United States, Canada and the European Union have all released documents concerning the regulatory oversight of plant made pharmaceuticals. Plants offer the possibility of producing needed quantities of antibodies and other therapeutic proteins at potentially significantly lower costs than systems based in animal, bacterial or viral cell-based processes. However, there are also concerns about containment of field trials and also any future commercial releases.

The regulatory responsibilities for GM plant based pharmaceuticals are basically the same as for GM food. In the United States, the USDA regulates the development and field production of plant-made pharmaceuticals, while the FDA regulates the evaluation, production and distribution of the pharmaceutical products of the plant-based production process. In Canada, the Canadian Food Inspection Agency (CFIA) regulates the development and field production of plant-made pharmaceuticals, while Health Canada regulates the evaluation, production and distribution of the pharmaceutical products of the plant-based production process.

The US discussion document is at:

<http://www.aphis.usda.gov/ppq/biotech/pdf/pharm-2002.pdf>

The Canadian document is at:

<http://www.inspection.gc.ca/english/plaveg/pbo/pbobbve.shtml>

In Europe the European Agency for the Evaluation of Medicinal Products has released a “points to consider” document at:

<http://www.emea.eu.int/pdfs/human/bwp/076402en.pdf>

The Biotechnology Industry Organisation announced in October 2002 that it would voluntarily impose a ban on planting GM crops designed to produce pharmaceuticals in US states which grow large quantities of the same crops for food use. However the announcement created a controversy in those states (especially Iowa), which are hoping to reap an economic boom from such crops, especially corn (Source; Washington Post 31 October 2002 via AgNet). BIO later amended their position to say “Detailed scientific and regulatory analyses confirm that plants that produce pharmaceutical and industrial products can be safely planted, grown and harvested in an agricultural region where all of the appropriate production, confinement, and handling practices are implemented” (Source: CropChoice 4 December 2002 via AgNet). In contrast, some organisations, such as the Grocery Manufacturers of America, would prefer that only non-food crops such as tobacco were used for pharmaceutical production.

#### *5.6.1.3 Prodigene pharmaceutical traits in grains and oilseeds*

The biotechnology company Prodigene has developed a number of GM corn varieties that express proteins that may have value as pharmaceuticals. These are being grown in field trials (or production scale-up) in Iowa and Nebraska. The varieties of corn have been genetically modified to produce:

- A protein found on the surface of HIV, the virus that causes AIDS, and which may be effective as an oral delivery system for an AIDS vaccine;
- Aprotinin, a protease inhibitor used in medical applications to control blood loss during surgery and in non-medical applications as a cell culture reagent;
- Avidin, a protein that binds with biotin to make useful products for the medical and biochemical diagnostics industry and has application in protein purification.
- Laccase, an industrial enzyme used for adhesives in the manufacturing of medium density fiberboard as well as in the detergent industry as an environmentally friendly <sup>3</sup>bio-bleach,<sup>2</sup>
- Brazzein, a low calorie, intense natural sweetener 2000 times sweeter than sucrose.
- Trypsin, a protease enzyme that has many uses including as an intermediate in pharmaceutical manufacturing and in the leather tanning and detergent industries.

Source: Fact sheet from Purdue University:

<http://www.agcom.purdue.edu/AgCom/Pubs/GQ/GQ-47.pdf>

Prodigene have also announced a collaborative research effort with FibroGen to produce recombinant gelatin in maize (Source: NewRx.com 24 July 2002 via AgNet).

#### *5.6.1.4 Epicyte produces monoclonal antibodies in plants*

Epicyte is a company associated with the Scripps Institute in San Diego. In August 2002 the company was granted a patent on its “Plantibodies” invention to produce monoclonal antibodies in plants. At present eleven antibody based drugs are on the market, all derived from animal cell cultures. The use of plants offers the opportunity to produce them at lower cost and in larger quantities. However, the breadth of the patent has created problems for other companies working on the same process. Already one European company is challenging the patent (Source: Ag-West Bulletin August 2002 via AgNet).

#### *5.6.1.5 Meristem produces enzyme to assist with digestion from corn*

A French company, Meristem Therapeutics has developed a GM corn variety that produces an enzyme, gastric lipase, that is given to patients with cystic fibrosis to aid digestion. The product, developed in collaboration with Solvay Pharmaceuticals, is undergoing advanced trials with human subjects. The corn is grown in Iowa, and the danger of cross pollination is avoided by using buffer zones, (1.6 kilometres), planting before or after neighbours have planted their corn crops, detasseling the plants, and most importantly using a male sterile corn that does not produce pollen. The production cost is estimated to be 14 times cheaper than production in the laboratory (Source: Associated Press 3 August 2002 via AgNet).

The company website is at:

<http://www.meristem-therapeutics.com/GB/intro.htm>

#### *5.6.1.6 Glycosylation patents*

The Dow Chemical Company has acquired a set of patents regarding protein glycosylation enabling the production of mammalian-like glycans in plants. The successful production of pharmaceuticals in plants requires glycosylation (addition of sugar molecules) which occurs naturally in mammalian cell culture production systems, but is often only partial in plant cells. The technology was originally developed at the University of Osaka (Source: DuPont Biotechnology Newsroom 12 November 2002 via AgNet).

#### *5.6.1.7 Growing GM pharmaceutical producing plants in the Ukraine*

The Ukraine government has entered into a joint venture with two biotechnology companies to develop and grow plant-based biopharmaceuticals. The two companies involved are Icon Genetics of Munich, which has developed a proprietary technology to produce pharmaceuticals in plants, and the Large Scale Biology Corporation from the US, which has developed downstream processing technology and biomanufacturing expertise (Source: Icon Press Release 3 December 2002 via AgNet).

### 5.6.2 GM poppies

The Western Australia Department of Agriculture has been granted a license by the Office of the Gene Technology Regulator to conduct a field trial of GM oil-seed poppies. These have been developed in conjunction with Glaxo Smith Kline with the aim of increasing the alkaloid content and offering the potential for a new industry (Source: <http://www.health.gov.au/ogtr/ir/dirs.htm#issued>).

### 5.6.3 Genome sequencing

A Japanese led international consortium set up to sequence the rice genome announced the completion of an advanced draft in December 2002 (Source: Press release 18 December 2002 via AgNet).

Philip Morris USA agreed to give North Carolina States University \$17.6 million to sequence the tobacco genome. It is expected to take nearly 5 years to map the 25,000 to 50,000 genes in the tobacco plant (Source: Associated Press 11 December 2002).

#### 5.6.4 Euro notes made from GM cotton

Most modern banknotes are printed on cotton based paper, which is durable and difficult to forge. The Euro is made from 100% cotton, and one of the European Central Bank's main suppliers of cotton is the US, where approximately 75% of the cotton crop is GM. Pro-GM spokespeople used this information to highlight inconsistencies in EU GM Legislation, while anti-GM groups called for future supplies to be obtained from countries which do not grow GM cotton, like Turkey (Source: The Times 1 January 2003 via AgNet).

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